

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
23 October 2003 (23.10.2003)

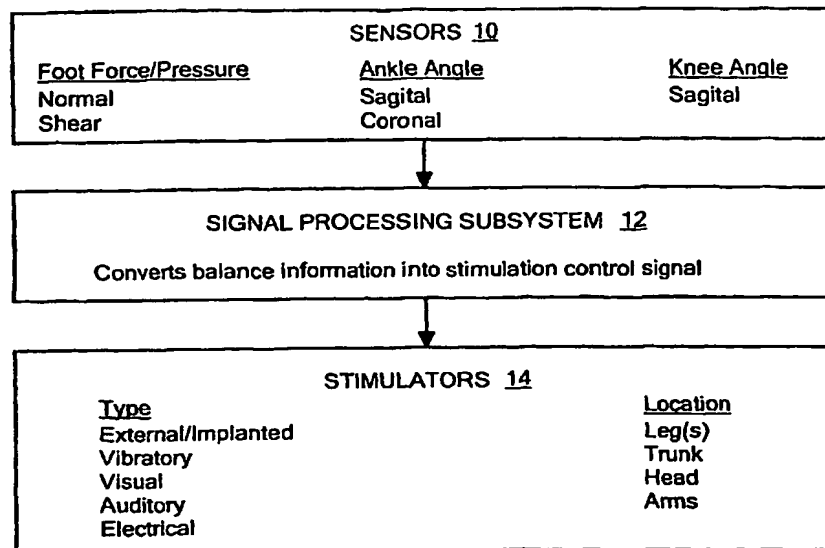
PCT

(10) International Publication Number  
**WO 2003/086235 A3**

- (51) International Patent Classification<sup>7</sup>: **A61B 5/103**,  
5/117
- (21) International Application Number:  
PCT/US2003/011338
- (22) International Filing Date: 14 April 2003 (14.04.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/372,148 12 April 2002 (12.04.2002) US
- (71) Applicant (for all designated States except US):  
TRUSTEES OF BOSTON UNIVERSITY [US/US];  
One Sherborn Street, Boston, MA 02215 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): ODDSSON, Lars,
- I., E. [IS/US]; 905 Beacon Street, Boston, MA 02215 (US).  
MEYER, Peter, F. [US/US]; 27 Elliot Street, Newton, MA  
02461 (US).
- (74) Agents: GAGNEBIN, Charles, L., III et al.; Weingarten,  
Schurgin, Gagnebin & Lebovici, LLP, Ten Post Office  
Square, Boston, MA 02109 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD,  
SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US,  
UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL



(57) Abstract: A feedback device for measuring balance related information, and for producing a stimulation of the skin that encodes that information in a way that is useful to the wearer of the device. At least one sensor (10) detects balance information and transmits at least one balance information signal to a signal processing subsystem (12).

WO 2003/086235 A3



SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- *of inventorship (Rule 4.17(iv)) for US only*

#### Published:

- *with international search report*

**(88) Date of publication of the international search report:**  
18 December 2003

**(48) Date of publication of this corrected version:**  
4 March 2004

**(15) Information about Correction:**  
see PCT Gazette No. 10/2004 of 4 March 2004, Section II

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

TITLE OF THE INVENTION  
SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119(e) to provisional patent application serial number 60/372,148, entitled "SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL", and filed April 12, 2002.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR  
DEVELOPMENT

N/A

BACKGROUND OF THE INVENTION

The present invention relates generally to systems for improving balance control, and more specifically to a feedback device which measures balance related information, and produces a stimulation of the skin that encodes that information.

It has been estimated that as much as 20% of the elderly population in the United States may be suffering from peripheral neuropathies, largely as a consequence of diabetes. Peripheral neuropathic patients exhibit increased body sway during quiet standing. Peripheral neuropathies have been associated with increased thresholds for the perception of ankle inversion/eversion and a reduced ability to maintain a unipedal (single footed) stance, suggesting a reduction in balance control while walking. Epidemiological evidence has linked peripheral neuropathies with an increased risk of falling. Postural responses to floor perturbations in peripheral (diabetic) neuropathy patients are delayed and are poorly scaled to the perturbation amplitude.

The most common symptom of peripheral neuropathies is a reduction in sensation from the soles of the feet. A number of studies have provided evidence that afferent information from the feet is an important part of the balance control system. A recent  
5 study on adaptation to microgravity suggests that foot sole pressure may be critical for triggering the anticipatory postural adjustments that are normally required to maintain balance during arm movements.

For the above reasons and others, it would be desirable to  
10 have a sensory substitution system that effectively provides information regarding foot sole pressure distribution to patients who are no longer able to acquire this information by natural means. The system should enable a patient wearing a device to achieve improved upright balance control, thereby reducing the  
15 patient's risk of falls and associated injuries. Such a system should further advantageously support integration of balance related feedback into the patient's unconscious postural control system, eventually eliminating the need for conscious effort in this regard.

#### BRIEF SUMMARY OF THE INVENTION

A feedback device is disclosed for measuring balance related information, and for producing a stimulation of the skin that encodes that information in a way that is useful to the wearer of  
25 the device. The disclosed device consists of at least one sensor for detecting balance information and for transmitting at least one balance information signal to a signal processing subsystem. The signal processing subsystem converts the received balance information signal into at least one stimulation control signal.  
30 The signal processing subsystem then transmits at least one stimulation control signal to at least one stimulator, which provides stimulation to a wearer of the device reflecting the

stimulation control signal received from the signal processing subsystem.

In one embodiment, an array of sensors are arranged under the soles of each foot of the wearer. The sensors operate to transduce the magnitude of pressure exerted on the foot sole at each sensor location into a balance information signal. A signal processing subsystem operates to convert the balance information signals obtained from the sensors into estimates of the location and magnitude of the resultant ground reaction force exerted on each foot, generally referred to as center-of-pressure, or "COP". The signal processing subsystem then encodes the estimated COP into stimulation control signals that drive elements of a stimulator array. Further in such an embodiment, the stimulator is made up of an array of vibrotactile stimulators for placement on the user's leg in one or more planes (also referred to as vibrator "levels") approximately parallel to the plane of the foot sole. Stimulators are arranged within each plane corresponding to at least four locations on each leg: anterior, posterior, medial, & lateral. In response to signals produced by the signal processing subsystem, the stimulator array provides vibrotactile stimulation of the skin of the leg representing the estimated COP. In such an embodiment, the disclosed system provides a portable, wearable device, by which the subject receives cutaneous stimulation on the leg regarding the location and magnitude of the ground reaction force under the ipsilateral foot. With training, a patient suffering from reduced plantar sensation will learn to make postural corrections in response to this stimulation in the same manner as a healthy person would react to changes in the pressure distribution under their feet.

Thus there is disclosed a sensory substitution system for providing information regarding foot sole pressure distribution to users who are no longer able to acquire this information by natural means. A user wearing this device will achieve improved

upright balance control, reducing their risk of falls and associated injuries. With practice, this encoded balance information provided by the device may be integrated into a patient's unconscious postural control system, eliminating the need for conscious balancing effort. The disclosed system may also be embodied so as to reduce the balance deficits caused by prolonged exposure to reduced weight bearing, as seen in patients recovering from prolonged bed rest or in astronauts returning to terrestrial gravity. Preventative treatments with the disclosed device may also reduce the hypersensitivity of foot soles in some users, which would otherwise contribute to postural deficits.

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

The invention will be more fully understood by reference to the following detailed description of the invention in conjunction with the drawings, of which:

Fig. 1 shows the structure and operation of an illustrative embodiment of the disclosed system;

Fig. 2 shows a circuit diagram of a portion of an illustrative embodiment of the disclosed system;

Fig. 3 is a flow chart showing steps performed during operation of an illustrative embodiment of the disclosed system;

Fig. 4 shows an illustrative embodiment of the disclosed system using a single level stimulation array;

Fig. 5 shows an illustrative embodiment of the disclosed system using a multi-level stimulation array;

Fig. 6 shows an illustrative embodiment of the disclosed system using a multi-level stimulation array in combination with a bi-axial goniometer;

Fig. 7 illustrates an example of force magnitude encoding in a multilevel stimulator embodiment; and

Figs. 8-12 show the mapping of balance information to stimulation points in an illustrative embodiment.

## DETAILED DESCRIPTION OF THE INVENTION

All disclosures of provisional patent application serial number 60/372,148, entitled "SENSORY PROSTHETIC FOR IMPROVED  
5 BALANCE CONTROL", and filed April 12, 2002, are hereby incorporated by reference herein.

Fig. 1 shows the structure and operation of an illustrative embodiment of the disclosed system. As shown in Fig. 1, sensors  
10 detect balance information that may represent foot force/pressure, such as normal and/or shear pressure, ankle angle, such as sagittal and/or coronal ankle angle, or knee angle, such as sagittal knee angle. The balance information detected by the sensors 10 is passed to a signal processing subsystem 12, which  
15 converts the balance information received from the sensors 10 into a stimulation control signal that is passed to the stimulators 14. The stimulators 14 operate in response to stimulation control signal, producing a stimuli to a user of the disclosed system representing the balance information detected by the sensors 10. The stimulators 14 may be of various types, including external  
20 and/or internal stimulators, and provide various types of stimuli, including vibratory, visual, auditory, and/or electrical stimuli. The stimulators 14 may be located on various parts of the body, including one or both legs, head, arms or trunk of the user.

Fig. 2 shows a circuit diagram of a portion of an illustrative embodiment of the disclosed system. As shown in Fig.  
25 2, a number of foot pressure sensors 16 transmit at least one balance information signal to one or more amplifiers 20 within a signal processing subsystem 18. The amplifiers 20 may, for example, include one or more LM324 analog amplifiers supplied by  
30 National Semiconductor Corporation. The amplified signals output from the amplifiers 20 are passed to a signal processor 22. In the example of Fig. 2, the signal processor includes analog to digital processing functionality, as well as program code storage

for code executable on the signal processor 22. The signal processor 22 may, for example, consist of a PIC 16F877 microcontroller, supplied by Microchip Technology, Inc. The signal processor 22 passes a digital stimulation control signal to one or more digital to analog converters 24, which convert the digital stimulation control signal to an analog stimulation control signal that is passed to one or more vibratory feedback devices 26. The vibratory feedback devices 26 provide a vibratory stimulus to a user wearing the vibratory feedback devices 26, such that the vibratory stimulus encodes and/or represents the balance information provided from the foot pressure sensors 16 to the signal processing subsystem 18. The digital to analog converters 24 may, for example, include one or more TLC7226IN, 8 bit, 4 channel digital to analog converters. The vibratory feedback devices may, for example, include one or more analog amplifiers, such as AD8534 analog amplifiers, supplied by Analog Devices, Inc., as well as a number of vibrators.

Fig. 3 is a flow chart showing steps performed during operation of an illustrative embodiment of the disclosed system. The steps shown in Fig. 3 may, for example be performed at least in part by the signal processing subsystem 18 shown in Fig. 2, for example under control of an assembly language program stored within and executed on the signal processor 22 shown in Fig. 2. As shown in Fig. 3, at step 28, the disclosed system reads balance information signals output from one or more sensors, and stores the values for subsequent processing. The disclosed system then operates to convert the stored sensor values into stimulation control values at step 30. The stimulation control values are then output at step 32.

An example of the processing performed by the signal processing subsystem to convert sensor values into stimulation control values is now provided. A formula describing the steps



performed by the signal processing subsystem to convert sensor values into stimulation control values is as follows:

$$\Theta_l(t) = \sum_{n=1}^N f_{nl}(t) \theta_{nl}, \quad R_l(t) = \sum_{n=1}^N f_{nl}(t) r_{nl}, \quad F_l(t) = \frac{1}{W} \sum_{n=1}^N f_{nl}(t) \quad (\text{Eq. 1})$$

5

where

$f_{nl}$  = normal force, approximately perpendicular to the plane of the foot sole, measured by sensor array element  $n$  under leg  $l$ ,

$\theta_{nl}$  = angular position of sensor array element  $n$  under leg  $l$ ,

10  $r_{nl}$  = radial position of sensor array element  $n$  under leg  $l$ ,

$N$  = total number of sensor array elements under leg  $l$ ,

$W$  = total body weight of the wearer,

$\Theta_l$  = angular position of center-of-pressure under leg  $l$ ,

$R_l$  = radial position of center-of-pressure under leg  $l$ ,

15  $F_l$  = portion of body weight supported by leg  $l$ , and,

$t$  = a variable representing discrete time

$$Q_{\Theta l}(t) = P_{\Theta} \Theta_l(t) + D_{\Theta} \frac{d\Theta_l(t)}{dt} + I_{\Theta} \sum_{z=t-u_{\Theta}}^t \Theta_l(z) + P_{\beta} \beta_l(t) + D_{\beta} \frac{d\beta_l(t)}{dt} + I_{\beta} \sum_{z=t-u_{\beta}}^t \beta_l(z) \quad (\text{Eq. 2})$$

20

$$Q_{Rl}(t) = P_R R_l(t) + D_R \frac{dR_l(t)}{dt} + I_R \sum_{z=t-u_R}^t R_l(z) + P_{\lambda} \lambda_l(t) + D_{\lambda} \frac{d\lambda_l(t)}{dt} + I_{\lambda} \sum_{z=t-u_{\lambda}}^t \lambda_l(z) \\ + P_{\alpha} \alpha_l(t) + D_{\alpha} \frac{d\alpha_l(t)}{dt} + I_{\alpha} \sum_{z=t-u_{\alpha}}^t \alpha_l(z) \quad (\text{Eq. 3})$$

$$Q_{Fl}(t) = P_F F_l(t) + D_F \frac{dF_l(t)}{dt} + I_F \sum_{z=t-u_F}^t F_l(z) \quad (\text{Eq. 4})$$

25

where

$\beta_l$  = the magnitude of the angle existing between the approximate longitudinal axis of foot  $l$  and the projection of the approximate longitudinal axis of the ipsilateral shank onto a plane

30 substantially parallel to the sole of foot  $l$ ,

$\lambda_1$  = the magnitude of the angle existing between the approximate longitudinal axis of shank 1 and a plane substantially parallel to the sole of foot 1,

$\alpha_1$  = the magnitude of the angle existing between a line substantially parallel to the longitudinal axis of shank 1 and a line substantially parallel to the longitudinal axis of the ipsilateral femur,

$z$  = a variable representing discrete time,

$d/dt$  = the operator indicating a discrete-time estimation of the first derivative,

$\Sigma$  = the summation operator,

$P_\theta, D_\theta, I_\theta, u_\theta, P_\beta, D_\beta, I_\beta, u_\beta, P_R, D_R, I_R, u_R, P_\lambda, D_\lambda, I_\lambda, u_\lambda, P_\alpha, D_\alpha, I_\alpha, u_\alpha, P_F, D_F, I_F,$  and  $u_F$  are time-invariant coefficients.

An example of an algorithm for the processing performed by software or firmware stored in and executed by a microcontroller in the signal processing subsystem is as follows:

ALGORITHM:

for  $v = 1$  to  $V$

for  $p = 1$  to  $P$

if  $\{(A_v \leq Q_{\lambda l}(t) < A_{v+1}) \cap (B_{p-} \leq Q_{\theta l}(t) \leq B_{p+})\} = \text{true},$

then  $S_{[v,p]l}(t) = h(Q_{\lambda l}(t), Q_{\theta l}(t))$

else  $S_{[v,p]l}(t) = 0$

end

end

where

subscripts  $J$  and  $K$  correspond to subscripts  $F$  and  $R$  in Equations 3 & 4:  $(J \equiv F \text{ and } K \equiv R)$  or  $(J \equiv R \text{ and } K \equiv F),$

$[v,p]$  denotes the spatial coordinates of an individual stimulator within the stimulation array,  $v$  being an integer denoting the

vertical index and  $p$  being an integer denoting the horizontal index of the stimulator at location  $[v,p]$ ,

$\cap$  denotes the logical AND operation,

$V$  = total number of horizontal rows in the stimulation array,

5  $P$  = total number of vertical columns in the stimulation array,

$A_j$  = the threshold of  $Q_{j1}(t)$  for activation of a stimulator in the  $j$ th row of the stimulator array,

$B_{j-}$  = the minimum value of  $Q_{01}(t)$  for activation of a stimulator in the  $j$ th column of the stimulator array,

10  $B_{j+}$  = the maximum value of  $Q_{01}(t)$  for activation of a stimulator in the  $j$ th column of the stimulator array,

$h(Q_{K1}(t), Q_{01}(t))$  is a piecewise-continuous function of  $Q_{K1}(t)$  and  $Q_{01}(t)$ , and

15  $S_{[v,p]1}$  is the magnitude of activation of stimulator  $[v,p]$  within the stimulator array attached to leg 1.  $S_{[v,p]1}$  may denote the amplitude or frequency of stimulation produced by stimulator  $[v,p]$ .

### Preferred Embodiment

20

In a preferred embodiment, with regard to the stimulators, 3 vibrator rows are used to encode load, 4 vibrator columns are used to encode polar center-of-pressure (COP) orientation, and vibrator activation voltage (proportional to frequency) is used to encode  
 25 polar radius of COP. Vibrator frequency is normalized over its active range to an elliptical ring with ranges of 1 to 8mm in the mediolateral direction and 2 to 20mm in the anteroposterior direction. These ranges were selected based upon the typical range of human movement during quiet stance and would be increased  
 30 in order to optimize the device for dynamic activities such as walking. The position of force transducers under the foot soles corresponds to a foot corresponding to a U.S. Men's size 9 shoe. Illustrative parameter values for an example of the preferred

embodiment are therefore provided for purposes of explanation as follows:

$$N = 7,$$

$$5 \quad r_1 = 75, r_2 = 80, r_3 = 90, r_4 = 120, r_5 = 70, r_6 = 80, r_7 = 115, \\ \text{(units in mm)}$$

$$\theta_1 = 0.70, \theta_2 = 1.05, \theta_3 = 1.39, \theta_4 = 1.74, \theta_5 = 2.09, \theta_6 = 4.36, \theta_7 = 4.89, \text{ (units in radians)}$$

$$V = 3, P = 4,$$

$$10 \quad J \equiv F, K \equiv R,$$

$$P_\theta = P_R = P_F = 1; P_\beta = P_\lambda = P_\alpha = 0; D_\theta = D_R = D_F = D_\beta = D_\lambda = D_\alpha = 0, I_\theta = I_R = I_F = I_\beta = I_\lambda = I_\alpha = 0,$$

$$A_1 = 0.25W, A_2 = 0.5W, A_3 = 0.75W,$$

$$B_{1-} = -0.25\pi \text{ rad}, B_{1+} = 0.25\pi \text{ rad}, B_{2-} = 0.25\pi \text{ rad}, B_{2+} = 0.75\pi \text{ rad},$$

$$B_{3-} = 0.75\pi \text{ rad}, B_{3+} = 1.25\pi \text{ rad}, B_{4-} = 1.25\pi \text{ rad}, B_{4+} = 1.75\pi \text{ rad},$$

$$15 \quad h \equiv (Q_{RI}(t) - R_o) \frac{V_{\max} - V_{\min}}{17} \text{ for } Q_{RI}(t) > R_o,$$

$$h \equiv 0 \text{ for } Q_{RI}(t) \leq R_o$$

$$\text{where } R_o = \sqrt{\frac{1}{\cos^2 Q_{\theta I}(t) + \frac{\sin^2 Q_{\theta I}(t)}{9}}}, V_{\max} = 5\text{Volts, and } V_{\min} = 2.5\text{Volts}$$

In an alternative embodiment, Equation 1 above also includes  
 20 calculation of the total shear force impinging on the sole of foot 1, and Equation 2 and/or 3 includes terms pertaining to the total shear force, the derivative of the total shear force, and the integral summation of the total shear force impinging on foot 1. Thus the representation of balance information by the stimulator  
 25 array reflects information regarding the shear forces impinging on the soles of the user's feet.

Neuropathic patients often encounter sustained elevated pressures under parts of their feet that result in skin damage and the development of an ulcer. Consistent with the algorithm above,  
 30 the disclosed system may operate such that signal processing

subsystem transmits signals to the stimulators reflecting the time histories of pressures or forces impinging on individual transducers within a sensor array. The resulting stimulation to a wearer of such an embodiment indicates when and where the forces or pressures impinging on an individual transducer within the sensor array have exceeded a predetermined instantaneous or time integral threshold.

While in the above algorithm the terms foot, shank and femur are used to describe body parts of a wearer of an embodiment of the disclosed system, those skilled in the art will recognize that other terms may be used in the alternative to describe the same parts. For example, alternative, corresponding terms to those used in the algorithm above include lower leg for shank, and upper leg for femur.

Fig. 4 shows an illustrative embodiment of the disclosed system using a single level stimulation array 40. As shown in Fig. 4, the illustrative embodiment includes a vibrotactile feedback array 40, a microprocessor controller subsystem 42, and a foot sole pressure sensor array 44. In the illustrative embodiment of Fig. 4, vibrotactile or electrotactile cutaneous feedback provided through the stimulation array 40 encodes position of foot Center-Of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. This stimulation array 40 is located adjacent to the skin of the leg or thigh. The location of active stimulator(s) on the skin in the transverse plane directly reflects the location of the foot Center-of-Pressure in the transverse plane.

The microprocessor controller subsystem 42 operates to convert electrical or mechanical signal(s) from the sensor array 44 into signal(s) which control the activity of elements within the feedback array 40. The microprocessor controller subsystem 42 may be implemented as a discrete system component or be imbedded

within the other components. The microprocessor controller subsystem 42 estimates the position of the Center-of-Pressure (COP) under the foot and/or the fraction of the body weight supported by the foot. These estimates are then used to produce  
5 an appropriate output signal to the feedback array 40. A "dead-zone" may be implemented such that Center-of-Pressure position within a certain range and/or foot load below a certain threshold may produce no output to the feedback elements.

Fig. 5 shows an illustrative embodiment of the disclosed  
10 system using a multi-level stimulation array. The illustrative embodiment of Fig. 5 includes an array of force sensing resistors (FSRs) 50 placeable under the soles of one or more feet of a user. Balance information from the array of force sensing resistors 50 is passed to a microprocessor data acquisition and processing  
15 subsystem 54. The subsystem 54 operates to convert the balance information it receives into stimulation control signals sent to a vibro-tactile array 52 located on one or more legs of the user. The vibro-tactile array 52 includes three vibrator levels 56, 58, and 59. A top view 60 of the vibrotactile array on the leg or  
20 legs of the user illustrates that each of the levels 56, 58 and 59 include four vibrators located in the front, back, and both sides of the leg or legs.

Fig. 6 shows an illustrative embodiment of the disclosed system using a multi-level stimulation array in combination with a  
25 bi-axial goniometer. As shown in Fig. 6, a force pressure sensor array 62 and a bi-axial goniometer 64 operate to provide balance information to a microprocessor data acquisition and processing subsystem 66. The bi-axial goniometer 64 provides information regarding detected ankle angle with regard to the angle of the  
30 user's foot to the corresponding lower leg. The stimulation array 68 on the user leg is shown as a multilevel vibrator array, and the top view 70 of the stimulation array 68 illustrates that each

level of vibrators in the stimulation array 68 includes four vibrators, mounted in the front, back, and both sides of the leg.

Fig. 7 illustrates an example of force magnitude encoding in a multilevel stimulator embodiment. Fig. 7 illustrates that a first, relatively low level force 72, may be encoded as a vibrational stimulus 74 on a lowest vibrator layer (or level) of the stimulation array. Similarly, a relatively high level force 80, may be encoded as a vibrational stimulus 82 on a highest vibrator layer (or level) of the stimulation array. Along these same lines, a force 76 between the forces 72 and 80 may be encoded as a vibrational stimulus 78 within a middle vibrator layer of the stimulation array. Thus Fig. 7 shows how a magnitude represented in the balance information signal, such as a ground reaction magnitude, can be communicated to the user through levels within a stimulator array attached or proximate to the user.

Figs. 8-12 show the mapping of balance information to stimulation points in an illustrative embodiment, and thus illustrate mapping of COP information onto a body part, in this case, a leg of the user. Fig. 8 shows a "dead zone" 86, representing a predetermined physical area under a user's foot. In an illustrative embodiment of the disclosed system, if a center of pressure is estimated to be located within the dead zone, no stimulus is provided to the user. In such a case, the user is significantly balanced on the foot in question. As shown in Fig. 8, in the event that a center of pressure 88 is determined to be within the predetermined dead zone, no vibrational stimulus is provided in any of the vibrators 90, 92, 94 or 96, shown within a single level of stimulators mounted on a user's leg in a plane parallel to an array of sensors mounted under the user's foot or feet.

Fig. 9 illustrates operation of an embodiment of the disclosed system in the event that a center of pressure 98 is estimated to be located towards the back of the user's foot.

Under such circumstances, a vibrator 96 located towards the back of the user's leg is shown providing a vibrational stimulus to the user.

5 Fig. 10 illustrates operation of an embodiment of the disclosed system in the event that a center of pressure 100 is estimated to be located towards the front of a user's foot. Under such circumstances, a vibrator 92 located towards the front of the user's leg is shown providing a vibrational stimulus to the user.

10 Fig. 11 illustrates operation of an embodiment of the disclosed system in the event that a center of pressure 102 is estimated to be located towards the front and right side of the user's foot. Under such circumstances, a vibrator 92 located towards the front of the user's leg, and a vibrator 94 located towards the right of the user's leg are shown providing a  
15 vibrational stimulus to the user.

Fig. 12 illustrates frequency encoded magnitude stimulus in an illustrative embodiment. In the embodiment illustrated by Fig. 12, a relative increase in vibration frequency in one or more vibrators within the stimulation array is triggered by an increase  
20 in the polar radial distance of the center of pressure from a coordinate frame located near the center of the foot, or from the edge of the dead zone.

As shown in Fig. 12, the radial distance of the center of pressure from the center of the user's foot may be encoded using  
25 the frequency of vibration caused to occur in one or more vibrators in the stimulation array. As shown in Fig. 12, an estimated center of pressure 104, located towards the front of the user's foot, and being relatively farther from the center of the user's foot, may be represented to the user by causing the  
30 vibrator 92 in the stimulation array to vibrate at a relatively higher frequency. Such a higher frequency vibration thus represents the further distance of the estimated center of pressure from the center of the foot to the user. For example,



the distance of the estimated center of pressure 104 from the center of the foot in Fig. 12 is greater than the distance of the estimated center of pressure 102 from the center of the foot in Fig. 11. Accordingly, the frequency of vibration of the vibrator 92 in Fig. 12 is greater than the frequency of vibration of the vibrators 92 and 94 in Fig. 11.

The disclosed system provides many and various advantages over previous systems. Specifically, the simplification of the balance information feedback provided by the disclosed system can more easily be integrated into the user's unconscious postural control system. The reduction of individual pressure signals by the disclosed system into an estimate of COP position and magnitude under each foot is easier to integrate into the postural control system than information regarding a number of separate pressure transducers.

A further advantage of the disclosed system relates to the coding of balance information using frequency modulation in addition to or as an alternative to amplitude modulation. Cutaneous stimulation has been shown to excite cutaneous mechanoreceptors on a 1 to 1 basis for a wide range of input frequencies. As a result, some cutaneous mechanoreceptors will respond to an artificial stimulation (vibrotactile or electrotactile) in the same manner as they would respond to a pressure stimulus. Simulating a natural pressure stimulus with an artificial one in this manner should facilitate the integration of this information into the unconscious balance control system.

Moreover, the location of feedback stimulators on the legs and oriented in a plane parallel to the plane of the foot sole should facilitate the integration of feedback information into the unconscious balance control system.

A number of specific variations and modifications are foreseen within the scope of the present invention. The following are some examples of variations and modifications:

1. The sensor array and/or stimulation array may be incorporated into a stocking, shoe, or boot.

2. The sensors may be embodied to acquire, encode, and provides feedback regarding shear forces under the user's foot or feet.

3. The sensors may be embodied to acquire, encode, and provide balance information regarding angle and or angular velocity of the lower leg with respect to the foot.

4. The disclosed system may be embodied to stimulate the cutaneous foot sole for the purpose of reducing postural deficits associated with long-term exposure to reduced foot loads, such as those incurred by bedridden patients on earth or astronauts in microgravity.

5. The disclosed system may be embodied to stimulate the cutaneous foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.

6. The disclosed system may be embodied to stimulate the skin of a part of the body other than the foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.

7. The disclosed system may be embodied to stimulate the cutaneous foot sole in response to pressure under the foot for the purpose of amplifying the sensation of pressure.

8. The disclosed system may be embodied to implement a signal processing method such that a range of COP positions and/or magnitudes produce no output from the feedback array (i.e. sensory "dead zone").

9. The mode of feedback may be embodied as tactile, vibrotactile, electrotactile, visual, thermal, and/or auditory.

10. The sensor array is implanted into or under the skin or within the body.

11. The feedback array may be implanted into or under the skin or within the body.

12. The stimulation array may be implanted such that the feedback elements are adjacent to or in contact with one or more sensory neurons or sensory nerves.

13. The sensor array may be affixed to or embedded within a prosthetic limb.

14. The communication between any or all of the device components may be wireless.

15. The sensor signals and/or feedback signals may be monitored remotely or recorded for the purpose of evaluating the effect or function of the device.

Those skilled in the art should appreciate that while the illustrative embodiments may implement the functions of the signal processing subsystem in computer software, these functions may alternatively be embodied in part or in whole using hardware components such as Application Specific Integrated Circuits, Field Programmable Gate Arrays, or other hardware, or in some combination of hardware components and software components.

While the invention is described through the above exemplary embodiments, it will be understood by those of ordinary skill in the art that modification to and variation of the illustrated embodiments may be made without departing from the inventive concepts herein disclosed. Accordingly, the invention should not be viewed as limited except by the scope and spirit of the appended claims.

## CLAIMS

What is claimed is:

1. A system for assisting the maintenance of balance, comprising:
  - 5 a plurality of sensors for detecting balance information, wherein said plurality of sensors is configured for placement under at least one foot of a user, wherein each sensor within said plurality of sensors transduces a detected magnitude of forces applied to said sensor, and wherein said plurality of sensors
  - 10 transmits at least one balance information signal representing said detected magnitude of forces applied to said each of said plurality of sensors;
    - a signal processing subsystem for receiving said at least one balance information signal from said plurality of sensors, and
    - 15 for converting said at least one balance information signal into at least one stimulation control signal, wherein said signal processing subsystem further operates to transmit said at least one stimulation control signal; and
    - at least one stimulator, responsive to said at least one
    - 20 stimulation control signal, for stimulating said user in a manner indicative of said detected magnitude of forces applied to said plurality of sensors.
2. The system of claim 1 wherein said plurality of sensors are
- 25 sensitive to forces oriented perpendicular to said plurality of sensors.
3. The system of claim 1 wherein said plurality of sensors are sensitive to forces oriented parallel to said plurality of
- 30 sensors.
4. The system of claim 1 wherein said plurality of sensors are sensitive to forces oriented parallel to said plurality of sensors

and forces oriented perpendicular to said plurality of said plurality of sensors.

5 5. The system of claim 1 wherein said plurality of sensors are mounted in a shoe.

6. The system of claim 1, wherein said plurality of sensors are mounted in a stocking.

10 7. The system of claim 1, wherein said plurality of sensors are mounted in a sandal.

15 8. The system of claim 1, wherein said plurality of sensors are insertable into a shoe.

9. The system of claim 1, wherein said plurality of sensors are insertable into a stocking.

20 10. The system of claim 1, wherein said plurality of sensors are insertable into a sandal.

11. The system of claim 1, wherein said plurality of sensors are insertable into skin of said user.

25 12. The system of claim 1, wherein said plurality of sensors are insertable under skin of said user.

13. The system of claim 1, wherein said plurality of sensors are insertable within a body of said user.

30 14. The system of claim 1 wherein said signal processing subsystem is further operable to:

convert said balance information signals received from said plurality of sensors into at least one estimate of a magnitude of force applied to a sole of said at least one foot; and

5 wherein said at least one stimulation control signal encodes said magnitude of force applied to said sole of said at least one foot.

15. The system of claim 1, wherein said signal processing subsystem is further operable to:

10 convert said at least one balance information signal into at least one estimate of a position of force applied to a sole of said at least one foot; and

15 wherein said at least one stimulation control signal encodes said position of force applied to said sole of said at least one foot.

16. The system of claim 1 wherein said signal processing subsystem is further operable to:

20 convert said at least one balance information signal into at least one estimate of an orientation of force applied to a sole of said at least one foot; and

25 wherein said at least one stimulation control signal encodes said orientation of force applied to said sole of said at least one foot.

17. The system of claim 1, wherein the signal processing subsystem is further operable to:

30 convert said at least one balance information signal into at least one estimate of a portion of a total body weight of said user applied to a sole said at least one foot and;

wherein said stimulation control signal encodes said portion of said total body weight of said user applied to said sole of said at least one foot.

18. The system of claim 1, wherein said signal processing subsystem is further operable to:

determine a magnitude of a resultant reaction force applied to a sole of said at least one foot by

calculating a sum equal to the total force applied to all sensors within said plurality of sensors, and

dividing said sum by a total body weight of said user.

19. The system of claim 1, wherein said at least one stimulator comprises an array of stimulators securable to a leg of said user.

20. The system of claim 1, wherein said at least one stimulator comprises an array of stimulators incorporated into a stocking.

21. The system of claim 1, wherein said at least one stimulator comprises at least one stimulator implantable into skin of said user.

22. The system of claim 1, wherein said at least one stimulator comprises at least one stimulator implantable within the body of said user.

23. The system of claim 22, wherein said at least one stimulator is placeable proximate with at least one sensory neuron of said user.

24. The system of claim 22, wherein said at least one stimulator is placeable proximate with at least one sensory nerve of said user.

25. The system of claim 1 wherein said at least one stimulator is operable to produce vibrational stimuli.

26. The system of claim 1, wherein said at least one stimulator is operable to produce electrical stimuli.

5 27. The system of claim 1, wherein said at least one stimulator is operable to produce electrocutaneous stimuli.

28. The system of claim 1, wherein said at least one stimulator is operable to produce auditory stimuli.

10

29. The system of claim 1, wherein said at least one stimulator is operable to produce visual stimuli.

15 30. The system of claim 1, wherein said at least one stimulator is operable to produce thermal stimuli.

31. The system of claim 1, wherein said at least one stimulator is configured for placement on at least one leg of said user.

20 32. The system of claim 1, wherein said at least one stimulator is configured for placement on the trunk of said user.

33. The system of claim 1, wherein said at least one stimulator is configured for placement on the head of said user.

25

34. The system of claim 1, wherein said at least one stimulator includes an array of stimulators mountable proximate to a leg of said user in a plane substantially parallel to a plane of an ipsilateral foot sole.

30

35. The system of claim 1 wherein said at least one stimulator is operable to stimulate a sole of said at least one foot.



36. The system of claim 1 wherein said at least one stimulator is responsive to said received stimulation control signal such that stimulus amplitudes, frequencies, and locations are indicative of at least one parameter describing forces applied to a sole of said  
5 at least one foot.

37. The system of claim 1, further comprising:

at least one sensor for transducing an angle between at least one foot and the ipsilateral lower leg, and for transmitting  
10 an ankle angle signal to said signal processing subsystem; and

wherein said signal processing subsystem receives said ankle signal, and determines said stimulation control signal, at least in part, responsive to said ankle angle signal.

15 38. The system of claim 1, further comprising:

at least one sensor for transducing an angle between at least one lower leg and the ipsilateral upper leg, and for transmitting a knee angle signal to said signal processing subsystem; and

20 wherein said signal processing subsystem receives said knee angle signal, and determines said stimulation control signal, at least in part, responsive to said knee angle signal.

39. A system for assisting the maintenance of balance during  
25 standing or gait, comprising:

at least one sensor for transducing an angle between at least one foot and an ipsilateral lower leg of a user, and for transmitting at least one balance information signal representing said angle;

30 a signal processing subsystem for receiving said balance information signal and for converting said at least one balance information signal into at least one stimulation control signal, and for transmitting said stimulation signal; and

at least one stimulator for receiving said at least one stimulation control signal and for stimulating the user in a manner indicative of said angle represented in said at least one balance information signal.

5

40. The system of claim 39, wherein said at least one sensor is operable to determine angles between said foot and said ipsilateral lower leg of said user projected onto a sagittal plane with respect to said user.

10

41. The system of claim 39, wherein said at least one sensor is operable to determine angles between said foot and said ipsilateral lower leg of said user projected onto a coronal plane with respect to said user.

15

42. The system of claim 39 wherein said at least one sensor is insertable into a shoe.

20

43. The system of claim 39 wherein said at least one sensor is insertable into a stocking.

44. The system of claim 39 wherein said at least one sensor is mounted within a shoe.

25

45. The system of claim 39 wherein said at least one sensor is mounted within a stocking.

30

46. The system of claim 39 wherein said signal processing subsystem is further operable to:

convert said at least one balance information signal into at least one estimate of a magnitude of an angle between at least one foot and an ipsilateral lower leg of said user; and

wherein said stimulation control signal encodes said magnitude of said angle between said at least one foot and said ipsilateral lower leg of said user.

5 47. The system of claim 39 wherein said at least one stimulator comprises an array of stimulators removably affixed to said ipsilateral lower leg of said user.

10 48. The system of claim 39 wherein said at least one stimulator comprises an array of stimulators incorporated into a stocking.

49. The system of claim 39, wherein said at least one stimulator is implantable into skin of said user.

15 50. The system of claim 39, wherein said at least one stimulator is implantable under skin of said user.

20 51. The system of claim 39, wherein said at least one stimulator is implantable within a body of said user.

52. The system of claim 39, wherein said at least one stimulator is placeable proximate to one or more sensory neurons of said user.

25 53. The system of claim 39, wherein said at least one stimulator is placeable proximate to one or more sensory nerves of said user.

54. The system of claim 39, wherein said at least one stimulator is operable to produce vibrational stimuli.

30 55. The system of claim 39, wherein said at least one stimulator is operable to produce electrical stimuli.

56. The system of claim 39, wherein said at least one stimulator is operable to produce electrocutaneous stimuli.

5 57. The system of claim 39, wherein said at least one stimulator is operable to produce auditory stimuli.

58. The method of claim 39, wherein said at least one stimulator is operable to produce visual stimuli.

10 59. The system of claim 39 wherein said at least one stimulator is operable to produce thermal stimuli.

60. The system of claim 39, wherein said at least one stimulator is afixable to at least one arm of said user.

15 61. The system of claim 39, wherein said at least one stimulator is afixable to a head of said user.

20 62. The system of claim 39, wherein said at least one stimulator is afixable to a trunk of said user.

25 63. The system of claim 39, wherein said at least one stimulator is placeable on at least one leg of said user in at least one plane approximately parallel to a plane of the ipsilateral foot sole.

64. The system of claim 39, wherein said at least one stimulator stimulates a sole of at least one foot of said user.

30 65. The system of claim 39, wherein said at least one stimulation control signal is indicative of angles between said least one foot and said ipsilateral lower leg of said user.

66. The system of claim 39, further comprising:

a plurality of sensors for detecting balance information, wherein said plurality of sensors is configured for placement under at least one foot of a user, wherein each sensor within said plurality of sensors transduces a detected magnitude of forces applied to said sensor, and wherein said plurality of sensors transmits at least one balance information signal representing said detected magnitude of forces applied to said each of said plurality of sensors; and

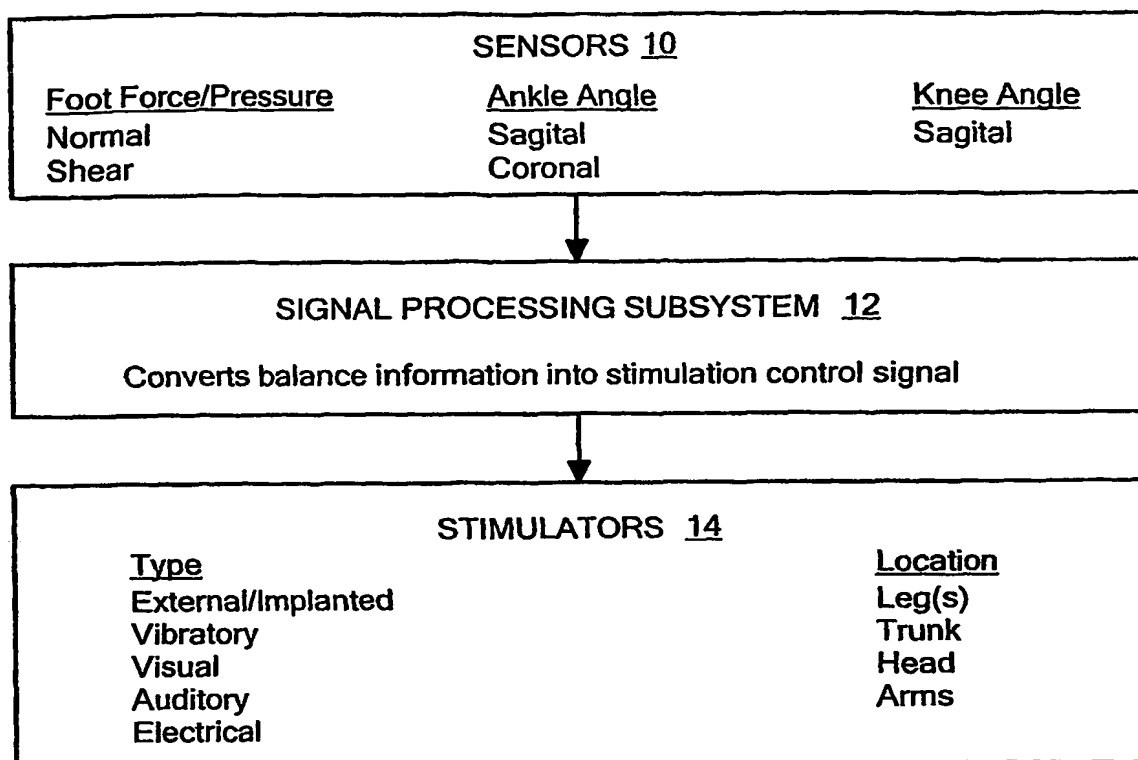
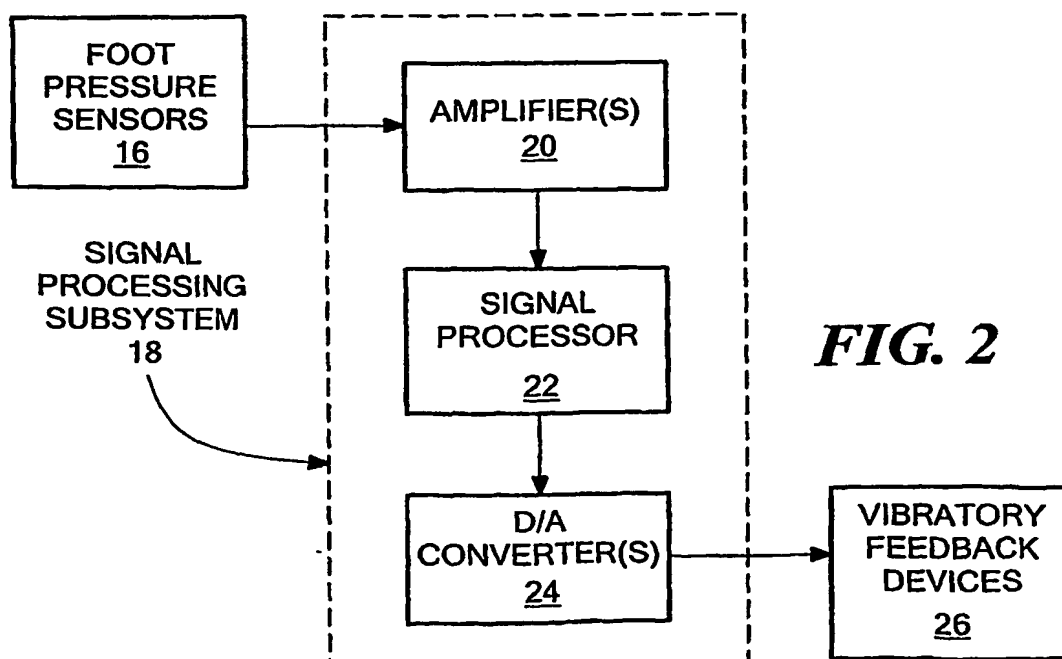
wherein said signal processing subsystem receives said balance information signal, and determines said stimulation control signal, at least in part, responsive to said at least one balance information signal.

67. The system of claim 39, further comprising:

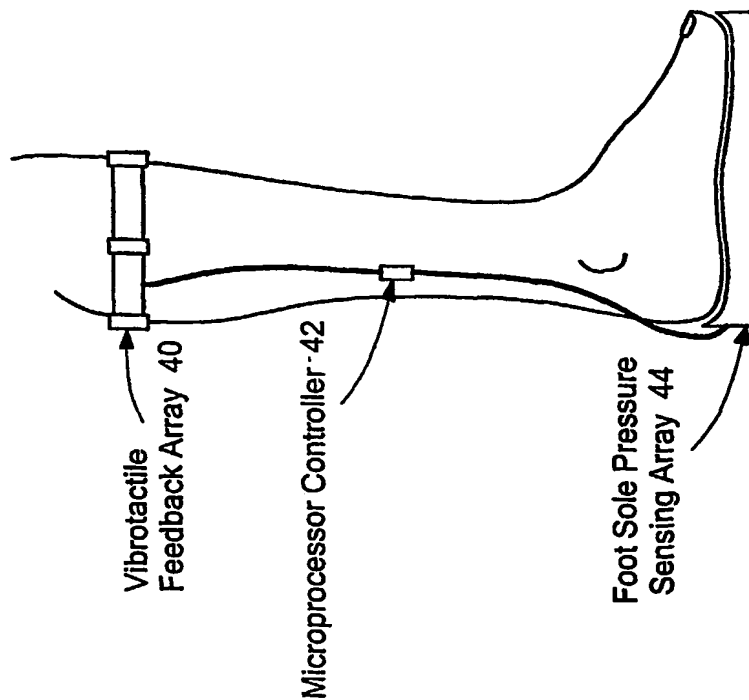
at least one sensor for transducing an angle between at least one lower leg and the ipsilateral upper leg, and for transmitting a knee angle signal to said signal processing subsystem; and

wherein said signal processing subsystem receives said knee angle signal, and determines said stimulation control signal, at least in part, responsive to said knee angle signal.

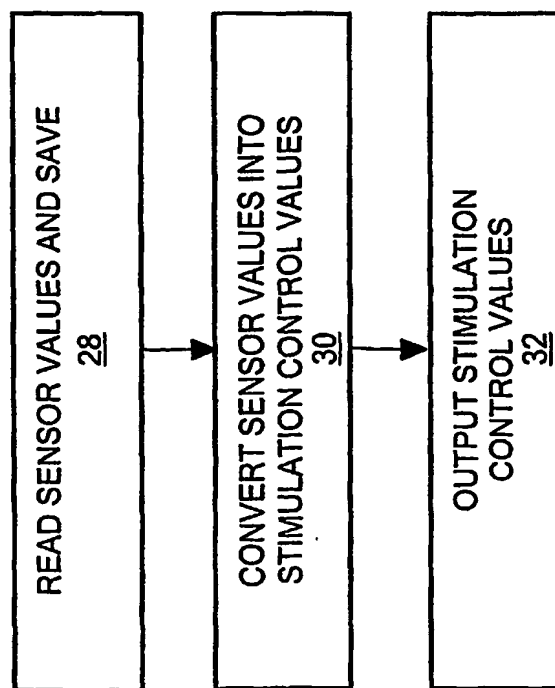
1/6

**FIG. 1****FIG. 2**

2/6



**FIG. 4**



**FIG. 3**

3/6

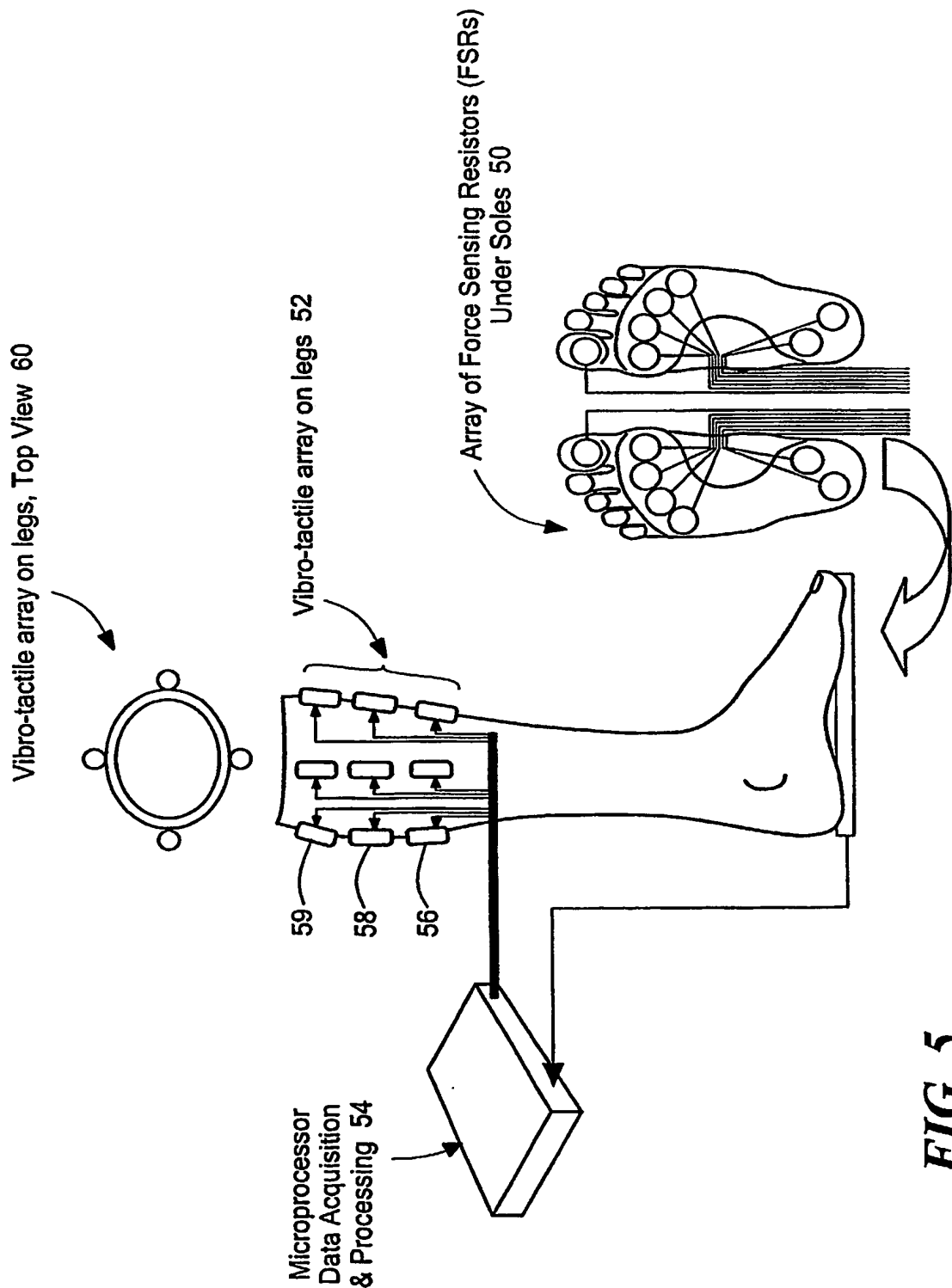
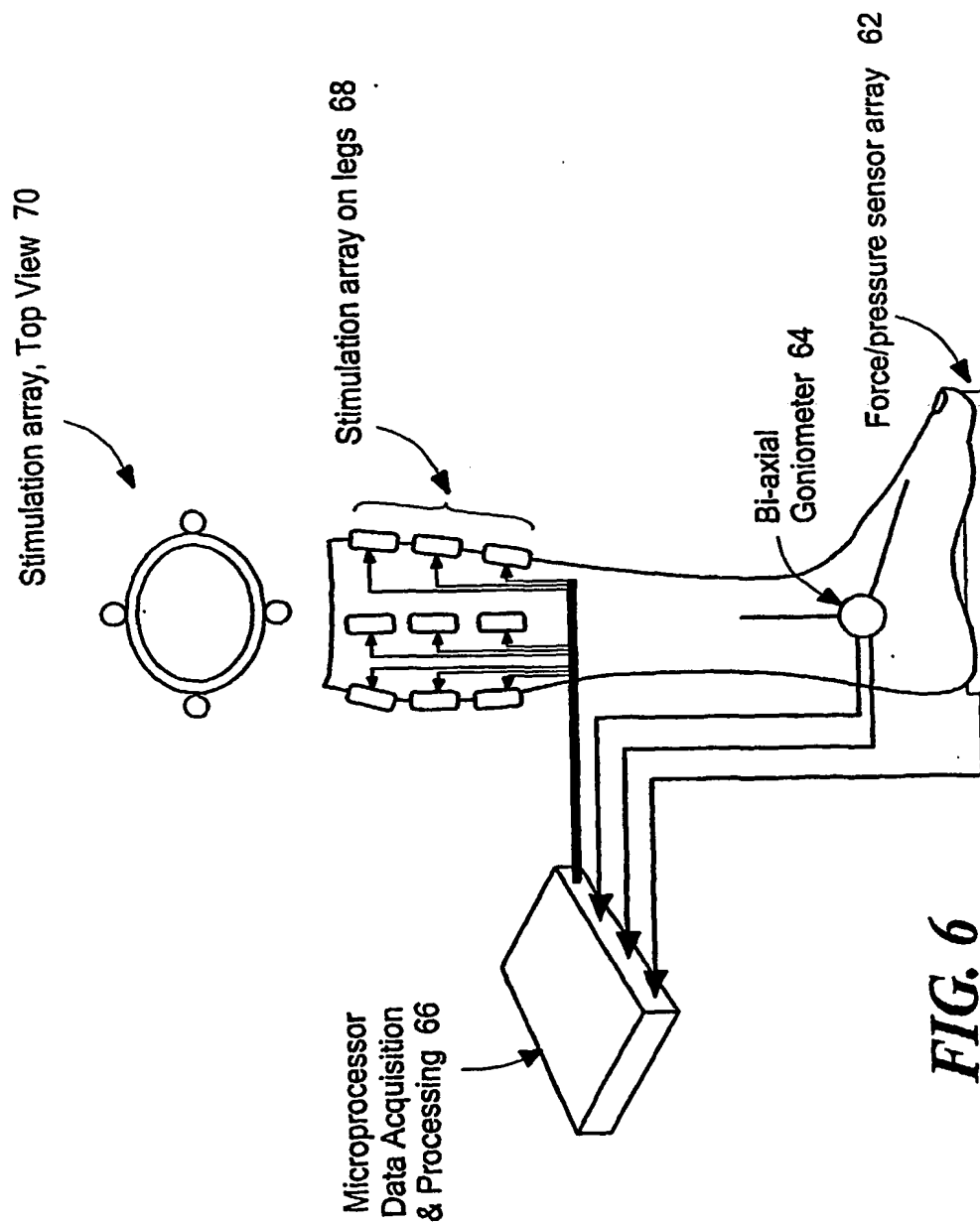


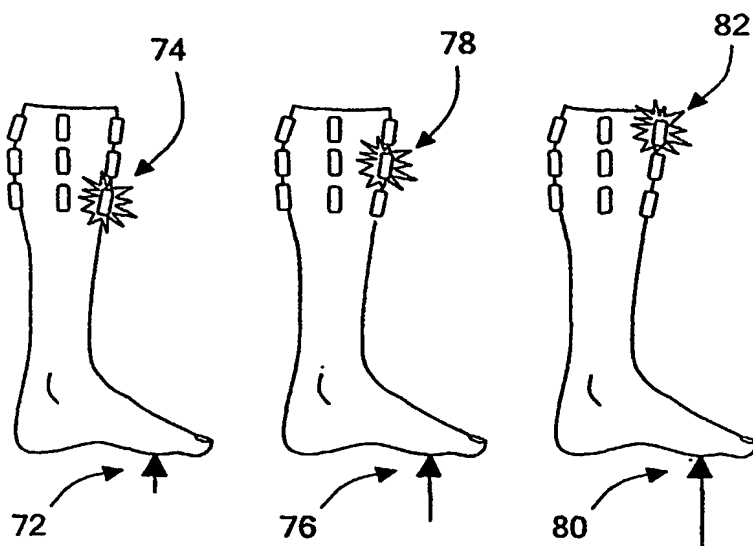
FIG. 5



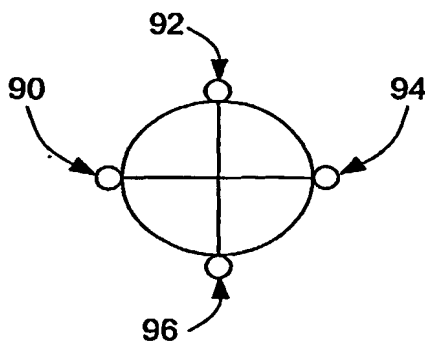
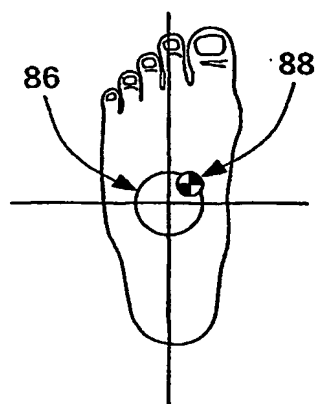
4/6



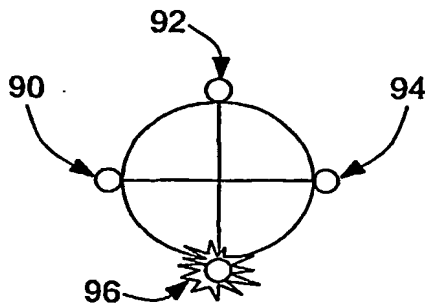
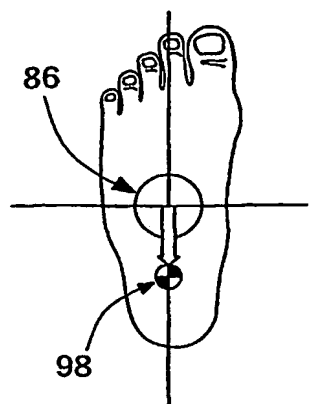
5/6



**FIG. 7**

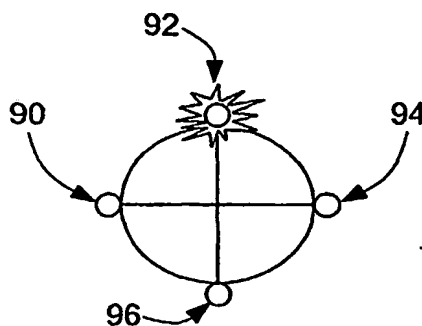
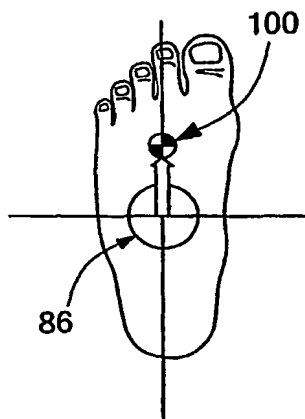


**FIG. 8**

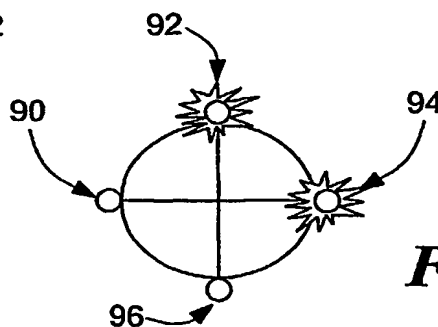
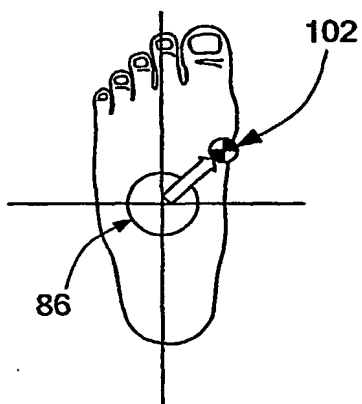


**FIG. 9**

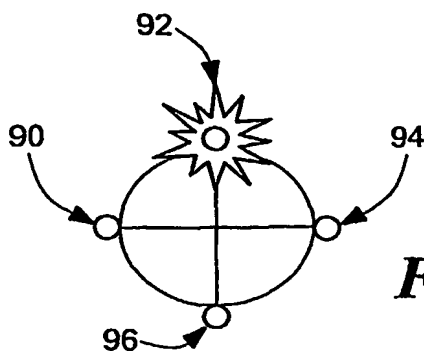
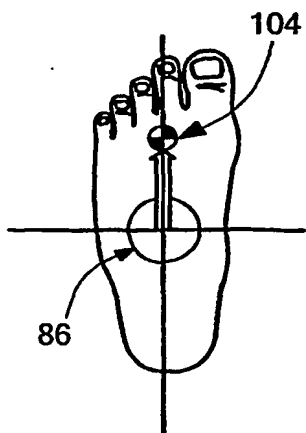
6/6



**FIG. 10**



**FIG. 11**



**FIG. 12**

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/11338

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/103, 5/117

US CL : 600/592

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/592,595,587,594,437; 602/16,26,5,23,20

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST: foot,sensor,balance,force,stimulation,stimulator,angle,ankle,knee,shoe,sandal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,174,294 B1 (CRABB et al) 16 January 2001, see whole document.	1,2,5,7,8,10,14-18,25-30
Y		39,54-59,63,66
Y	US 4,745,930 A (CONFER) 24 May 1988, see whole document.	32,37-
Y	US 5,678,448 A (FULLEN et al) 21 October 1997, see whole document.	42,44,46,62,65,67
		6,9,43,45

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 August 2003 (27.08.2003)

Date of mailing of the international search report

Authorized officer

Brian Szmat

Telephone No. (703) 308-0858

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230